

**UNITED STATES DISTRICT COURT  
DISTRICT OF MINNESOTA**

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SUSAN WEBB,

Civil No. 13-1947 (JRT/JJK)

Plaintiff,

v.

**MEMORANDUM OPINION  
AND ORDER AFFIRMING  
ORDER OF MAGISTRATE JUDGE**

ETHICON ENDO-SURGERY, INC.,

Defendant.

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William L. Tilton and Grace Davies, **TILTON & DUNN, P.L.L.P.**, 101 Fifth Street East, Suite 2220, St. Paul, MN 55101, for plaintiff.

David R. Noteware and Timothy E. Hudson, **THOMPSON & KNIGHT LLP**, One Arts Plaza, 1722 Routh Street, Suite 1500, Dallas, TX 75201; and Sheryl A. Bjork, **BOWMAN & BROOKE LLP**, 150 South Fifth Street, Suite 3000, Minneapolis, MN 55402, for defendant.

This is a products liability, negligent manufacturing, failure to warn, and breach of warranty action brought by Plaintiff Susan Webb (“Webb”) against Defendant Ethicon Endo-Surgery, Inc. (“Ethicon”). On June 26, 2015, Webb moved to compel production of all Product Inquiry Verification Reports (“PIVRs” or “incident reports”) – customer complaint reports – for the TX stapler line, as well as any emails related to those PIVRs. On July 10, 2015, United States Magistrate Judge Jeffrey J. Keyes issued an oral order granting in part Webb’s motion to compel. Magistrate Judge Keyes ordered Ethicon to produce additional PIVRs from only the following categories: firing issues; found during analysis; malformed staples; miscellaneous; not specified; would not fire; and non-specific noise. The Magistrate Judge denied Webb’s motion to the extent it sought

PIVRs beyond those categories and also denied the motion to compel production of emails relating to the PIVRs.

This matter is now before the Court on Webb's appeal of the Magistrate Judge's order. Because the Court finds that the Magistrate Judge's order was neither clearly erroneous nor contrary to law, the Court will overrule Webb's objection.

## **BACKGROUND<sup>1</sup>**

### **I. DOCUMENT REQUEST NO. 40**

On June 6, 2014, Webb served Ethicon with Document Request Number 40 ("Document Request No. 40"). (Decl. of Grace Davies ("Davies Decl."), Ex. A at 7-9, June 26, 2015, Docket No. 356.) Document Request No. 40 has multiple subparts and states, in its entirety, as follows:

#### **Document Request No. 40:**

- a. All Premarket Notification Applications which mention any Ethicon Proximate Linear Staplers, pursuant to section 510(k) of the U.S. Food, Drug and Cosmetic Act and 21 C.F.R. §807.81, and all supplements or revisions to any related Premarket Notification;
- b. All Device History Record documents relating to Ethicon Proximate Linear Staplers, as defined by 21 C.F.R. §803.3(i) and required by 21 C.F.R. §820.184(a) through (f);
- c. All documents relating to the Quality System Record for Ethicon Proximate Linear Staplers as required by 21 C.F.R. §820.186;
- d. Any and all documents related to any Complaint File as defined by 21 C.F.R. §820.3(b) and required by 21 C.F.R. §820.198(a) through (g), relating to:

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<sup>1</sup> A full factual background of the underlying events in this case can be found in the Court's previous Order. *See Webb v. Ethicon Endo-Surgery, Inc.*, No. 13-1947, 2014 WL 7213202, at \*1-\*4 (D. Minn. Dec. 17, 2014).

- i. Ethicon Proximate Linear Staplers;
- ii. All other stapler devices, including any software and components thereof, that has been at any time identified as “Substantially Equivalent” to Ethicon Proximate Linear Staplers (including the TX series) in any Premarket Notification for this or any other stapler product, pursuant to section 510(k) of the U.S. Food, Drug, & Cosmetic Act;
- e. All Quality Audit documents, as defined by 21 C.F.R. §820.3(t) and as required by 21 C.F.R. §820.22, relating to Ethicon Proximate Linear Staplers and other stapler products made in whole or part in Juarez, Mexico;
- f. All Nonconformity documents relating to the Subject Ethicon Proximate Linear Staplers, as defined by 21 C.F.R. §820.3(q), including the procedures required by 21 C.F.R. §820.90;
- g. Any and all documents related to all corrective and preventative actions (CAPA) as required by 21 C.F.R. §820.100, relating to the Ethicon Proximate Linear Staplers and to any other stapler product which relies on a Vision-type system for seeking to identify the presence of staples during production; and any component thereof, including, but not limited to Quality Improvement Requests, Continuous Improvement Requests, QIR logs, and non-conformance procedures and training; this includes minutes of any meetings of any committee of defendant related to CAPA matters related to defendant’s facilities in Juarez, Mexico;
- h. Any and all documents related to changes or modifications to the manufacture and production of Ethicon Proximate Linear Staplers and any component parts thereof, including, but not limited to, changes or deviations to specifications and guidelines, and all risk assessments, internal risk assessment memos, Top Level Design Control Procedures including risk analysis and human factors consideration, internal summary memos, correspondence, validation processes, testing, and approvals generated therefrom;
- i. Any Ethicon Policy and/or Procedure for handling reports of non-working products, including but not limited to any products approved by the FDA;
- j. Copies of all legal complaints and claim letters received by Ethicon (including Johnson and affiliated entities) wherein any allegation is made

that an injury occurred due to an Ethicon surgical stapler or that a stapler was made with staples missing.

(*Id.* at 7-8.)

On August 8, 2014, Magistrate Judge Jeanne J. Graham granted in part Webb's motion to compel production of the documents covered by Document Request No. 40, along with several other document requests. (Order ("August 8 Order"), Aug. 8, 2014, Docket No. 144.) Ethicon requested permission to file a motion for clarification and reconsideration of the August 8 Order, and on August 18, 2014, Magistrate Judge Graham denied that request. (Order ("August 18 Order"), Aug. 18, 2014, Docket No. 150.) Both parties objected to Magistrate Judge Graham's orders, and on January 26, 2015, this Court overruled both objections and affirmed the Magistrate Judge's rulings. (Mem. Op. & Order Affirming Orders of Magistrate Judge, Jan. 26, 2015, Docket No. 264.) In this Court's January 26 Order, the Court explained that the Magistrate Judge's orders struck a careful balance between allowing discovery into all of Ethicon's surgical staplers and too narrowly restricting discovery, which would risk Ethicon withholding potentially relevant information about similar flaws in staplers with related designs. (*Id.* at 10-11, 13 & n.2.)

## **II. JULY 10, 2015 HEARING**

On December 5, 2014, Webb filed a Second Motion to Compel PIVRs. (Pl.'s Second Mot. to Compel, Dec. 5, 2014, Docket No. 228.) PIVRs are customer complaints for Ethicon products. Each PIVR is classified as belonging to a particular Voice of Customer ("VOC") category. Ethicon has 94 VOC categories in total.

Following a hearing on December 19, 2014, Magistrate Judge Keyes ordered Ethicon to produce all PIVRs relating to the following VOC coding categories: Missing Staples, Incomplete Staple Line, Would Not Staple, Firing Empty, Hemostasis Controllable, Hemostasis Intervention, Leak Controllable, Leak Intervention, Packaging Device Issue, and Patient User Related Issue. (Oral Order on Pl.'s Second Mot. to Compel, Dec. 19, 2014, Docket No. 249.) Magistrate Judge Keyes denied Webb's motion to compel disclosure of PIVRs from 19 additional VOC categories. (*Id.*) Ethicon subsequently produced approximately 20,000 documents, including 800 PIVRs, roughly 670 of which are unique (not duplicates).

Nevertheless, Webb insisted that Ethicon was refusing to produce a multitude of PIVRs and related emails, and on June 26, 2015, Webb filed an additional motion to compel. (Pl.'s Mot. to Compel Disc. & for Sanctions, June 26, 2015, Docket No. 351.) On July 10, 2015, Magistrate Judge Keyes held a motion hearing on Webb's motion to compel. At the hearing, the parties disagreed about the number of outstanding PIVRs; Webb suggested that approximately 1,000 PIVRs have not been produced, and Ethicon posited that for all 94 VOC categories, the number was closer to 2,200. With respect to emails related to the PIVRs, Ethicon estimated that it would cost in the neighborhood of \$2,000,000 to identify and produce the emails, while Webb maintained that the cost would be lower because they have agreed to limit the number of custodians from whom they seek emails.

Based on the parties' arguments, Magistrate Judge Keyes concluded that the production of PIVRs relating to seven additional categories is appropriate. The

Magistrate Judge denied Webb’s request for emails relating to PIVRs, finding Webb’s request “overly broad and the cost of production outweighs benefits to be derived from the e-mail discovery.” (Mins. for July 10, 2015 Proceedings Held Before Magistrate Judge Jeffrey J. Keyes, July 10, 2015, Docket No. 368.) Webb appealed the ruling on the PIVR-related emails, and this matter is now before the Court on Webb’s objection. (Pl.’s Objection to the Order Dated July 10, 2015 (“Objection”), July 24, 2015, Docket No. 372.)

## **DISCUSSION**

### **I. STANDARD OF REVIEW**

A magistrate judge has broad discretion over matters of discovery. *Shukh v. Seagate Tech., LLC*, 295 F.R.D. 228, 238 (D. Minn. 2013). A district court’s review of a magistrate judge’s order on a nondispositive matter is “extremely deferential.” *Roble v. Celestica Corp.*, 627 F. Supp. 2d 1008, 1014 (D. Minn. 2007); *see also United States v. Raddatz*, 447 U.S. 667, 673 (1980). The Court will reverse such an order only if it is clearly erroneous or contrary to law. *See* 28 U.S.C. § 636(b)(1)(A); Fed. R. Civ. P. 72(a); D. Minn. LR 72.2(a)(3). For an order to be clearly erroneous, the district court must have a “definite and firm conviction that a mistake has been made.” *Lisdahl v. Mayo Found.*, 633 F.3d 712, 717 (8<sup>th</sup> Cir. 2011) (quoting *Anderson v. Bessemer City*, 470 U.S. 564, 573 (1985)).

## II. MOTION TO COMPEL

Webb seeks the production of all remaining PIVRs for all 94 VOC categories, as well as any related emails. Under Federal Rule of Civil Procedure 26, “[p]arties may obtain discovery regarding any nonprivileged matter that is relevant to any party’s claim or defense . . . . Relevant information need not be admissible at the trial if the discovery appears reasonably calculated to lead to the discovery of admissible evidence.” Fed. R. Civ. P. 26(b)(1). Under the wording of Rule 26(b)(1), discoverable evidence is limited to relevant information. The scope of discoverable evidence is further limited by Rule 26(b)(2)(C)(iii), under which “the court **must** limit the frequency or extent of discovery otherwise allowed by these rules or by local rule if it determines that . . . the burden or expense of the proposed discovery outweighs its likely benefit . . . .” Fed. R. Civ. P. 26(b)(2)(C)(iii) (emphasis added).

Webb argues that this Court’s January 26 Order and Magistrate Judge Graham’s August 2014 orders allowed discovery of all TX line PIVRs and related emails. Webb is correct that those orders required the production of all relevant documents in connection with Document Request No. 40, but the orders are, of course, to be read and followed in conjunction with the Federal Rules of Civil Procedure. Although Webb has amended her complaint to include claims for failure to warn and breach of warranty, the information she seeks must be not only relevant to her claims but also not unduly burdensome to produce.

The Court concludes that the Magistrate Judge’s ruling with respect to the emails was neither clearly erroneous nor contrary to law. Webb argues that Ethicon’s PIVR-

related “emails will either show a rigorous process by defendant to truly understand what is causing the hundreds of stapler failures or they will reflect defendant’s shallow efforts characterized by the repeated use of boilerplate language in the PIVRs.” (Objection at 11-12.) Irrespective of whether such emails would be relevant, if the burden of producing them outweighs the value of the emails’ production, the Federal Rules of Civil Procedure permit the court to restrict the scope of discovery. Fed. R. Civ. P. 26(b)(2)(C)(iii).

The burden of production in this case is significant. Ethicon estimated that production of the additional PIVRs and PIVR-related emails would cost \$2,000,000 and involve sifting through emails from hundreds of custodians. Although Webb maintains that the cost would be much lower and the number of custodians fewer, when asked directly by the Magistrate Judge at the hearing for an alternative estimated cost and scope, Webb’s counsel was unable to provide different figures, responding, “It’s hard for me to know how many are there.” Webb’s objection goes into great detail about the agreement reached between the parties to narrow the scope of discovery, but it offers no alternative cost estimate.

The Magistrate Judge was aware that the parties had agreed to narrow the scope when he concluded that Webb’s request was still too costly and overbroad. Even if Webb is correct that the \$2,000,000 estimate is overstated, substantial room remains within which the Magistrate Judge could credibly determine that the cost was too great to warrant compelling production. Without a time and cost projection against which to compare the Magistrate Judge’s conclusion, the Court finds that the Magistrate Judge’s

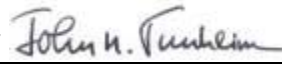


determination was not clearly erroneous.<sup>2</sup> Therefore, the Court will overrule Webb's objection and affirm the order of the Magistrate Judge.

### ORDER

Based on the foregoing, and all the files, records, and proceedings herein, **IT IS HEREBY ORDERED** that Webb's objection [Docket No. 372] is **OVERRULED** and the Order of the Magistrate Judge on Plaintiff's [351] Motion to Compel Discovery dated July 10, 2015 [Docket No. 368] is **AFFIRMED**.

DATED: September 22, 2015  
at Minneapolis, Minnesota.

s/   
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JOHN R. TUNHEIM  
Chief Judge  
United States District Court

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<sup>2</sup> The Court reminds the parties that objections to a Magistrate Judge's order or report and recommendation are not merely a chance to rehash the same arguments rejected by the Magistrate Judge. Objections to a Magistrate Judge's findings and recommendations are an integral part of the federal system when warranted, but "Congress created this process to promote judicial economy and there is no net efficiency when the losing party uses the objection process as a second bite at the apple." *Ayotte v. Am. Economy Ins. Co.*, No. 09-57, 2010 WL 10862749, at \*1 (D. Mont. Dec. 10, 2010). Where objections cite no case law and merely repeat the same arguments presented to the Magistrate Judge, hoping for a different result, the Court must retread ground already covered by the Magistrate Judge. "This duplication of time and effort wastes judicial resources, rather than saving them, and runs contrary to the purposes of the Magistrates Act." *Howard v. Sec'y of Health & Human Servs.*, 932 F.2d 505, 509 (6<sup>th</sup> Cir. 1991). If the parties are not simply disappointed with the result but have a good faith belief that the Magistrate Judge has committed clear error or reach a result that is contrary to law, the Court certainly welcomes objection to that decision. But particularly on discovery matters, where Magistrate Judges have considerable discretion, the Court expects objecting parties to present specific arguments and support for the position that the Magistrate Judge erred as a matter of law, rather than reciting facts that were before the Magistrate Judge and asking for the opposite outcome.